# **Complete Summary**

#### **GUIDELINE TITLE**

Management of adnexal masses.

# **BIBLIOGRAPHIC SOURCE(S)**

American College of Obstetricians and Gynecologists (ACOG). Management of adnexal masses. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2007 Jul. 14 p. (ACOG practice bulletin; no. 83). [116 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

# **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

**CATEGORIES** IDENTIFYING INFORMATION AND AVAILABILITY

**DISCLAIMER** 

# **SCOPE**

# **DISEASE/CONDITION(S)**

Adnexal masses (ovarian neoplasms)

# **GUIDELINE CATEGORY**

Diagnosis Evaluation Management Risk Assessment

#### **CLINICAL SPECIALTY**

Nuclear Medicine Obstetrics and Gynecology Oncology Surgery

#### **INTENDED USERS**

Physicians

# **GUIDELINE OBJECTIVE(S)**

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the most recent data on imaging modalities, operative assessment of the adnexal mass, and preoperative models to predict the probability of ovarian malignancy

#### **TARGET POPULATION**

Women of all ages with suspected ovarian neoplasm

#### INTERVENTIONS AND PRACTICES CONSIDERED

### **Evaluation and Diagnosis**

- 1. History and physical examination
  - Assessment of risk factors
  - Pelvic examination
  - Premenopausal versus postmenopausal women
- 2. Differential diagnosis
  - Benign versus malignant masses
  - Gynecologic versus nongynecologic origin
- 3. Imaging
  - Gray-scale transvaginal ultrasound
  - Other imaging modalities including color Doppler ultrasound, computed tomography scan, magnetic resonance imaging, positron emission tomography scan (considered but not recommended for routine use)
- 4. Serum markers
  - CA 125
  - Beta-human chorionic gonadotropin (hCG)
  - Lactic dehydrogenase (LDH)
  - Alpha-fetoprotein (AFP)
- 5. Aspiration of nonunilocular cyst

# Management

- 1. Observation
- 2. Referral to a gynecologic oncologist
- 3. Expectant management of adnexal masses in pregnancy
- 4. Operative assessment
  - Laparotomy versus laparoscopy for unilateral masses

- Cystectomy
- Unilateral oophorectomy
- Salpingo-oophorectomy
- Hysterectomy
- Bilateral salpingo-oophorectomy
- Conservative approaches

#### **MAJOR OUTCOMES CONSIDERED**

- Incidence of benign adnexal masses
- Incidence of malignant adnexal masses
- Surgical complication rates
- Mortality
- Sensitivity and specificity of diagnostic tests

#### **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

# DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and January 2007. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

#### **NUMBER OF SOURCE DOCUMENTS**

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1** Evidence obtained from well-designed controlled trials without randomization.
- **II-2** Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III** Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

#### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician—gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- **Level C** Recommendations are based primarily on consensus and expert opinion.

#### **COST ANALYSIS**

Published cost analyses of ultrasonography and other imaging modalities were reviewed.

#### **METHOD OF GUIDELINE VALIDATION**

Internal Peer Review

#### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

# **RECOMMENDATIONS**

#### **MAJOR RECOMMENDATIONS**

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

# The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):

- In asymptomatic women with pelvic masses, whether premenopausal or postmenopausal, transvaginal ultrasonography is the imaging modality of choice. No alternative imaging modality has demonstrated sufficient superiority to transvaginal ultrasonography to justify its routine use.
- Specificity and positive predictive value of CA 125 level measurements are consistently higher in postmenopausal women compared with premenopausal women. Any CA 125 elevation in a postmenopausal woman with a pelvic mass is highly suspicious for malignancy.
- Simple cysts up to 10 cm in diameter on ultrasound findings are almost universally benign and may safely be followed without intervention, even in postmenopausal patients.
- Unilateral salpingo-oophorectomy or ovarian cystectomy in patients with germ cell tumors, stage I stromal tumors, tumors of low malignant potential, and stage IA, grade 1–2 invasive cancer who undergo complete surgical staging and who wish to preserve fertility does not appear to be associated with compromised prognosis.

# The following recommendations and conclusions are based primarily on consensus and expert opinion (Level C):

 Women with ovarian cancer whose care is managed by physicians who have advanced training and expertise in the treatment of women with ovarian cancer, such as gynecologic oncologists, have improved overall survival rates compared with those treated without such collaboration.  Most masses in pregnancy appear to have a low risk for both malignancy and acute complications and, thus, may be considered for expectant management.

#### Definitions:

#### **Grades of Evidence**

- I Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1** Evidence obtained from well-designed controlled trials without randomization.
- **II-2** Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III** Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

#### **Levels of Recommendation**

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- **Level C** Recommendations are based primarily on consensus and expert opinion.

# **CLINICAL ALGORITHM(S)**

None provided

# **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

Appropriate evaluation and diagnosis of adnexal masses, and referral of women with newly diagnosed masses to a gynecologic oncologist

#### **POTENTIAL HARMS**

Surgical complications

# **CONTRAINDICATIONS**

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# **Aspiration of Nonunilocular Cyst Fluid**

- Aspiration of nonunilocular cyst fluid for both diagnosis and treatment of an adnexal mass may seem guicker, less invasive, and less expensive than surgery; however, it is typically regarded as contraindicated in postmenopausal women for several reasons, especially when there is a suspicion for cancer. First, diagnostic cytology has poor sensitivity to detect malignancy, ranging from 25% to 82%. In addition, even when a benign mass is aspirated, the procedure often is not therapeutic. Approximately 25% of cysts in perimenopausal and postmenopausal women will recur within 1 year of the procedure. Finally, aspiration of a malignant mass may induce spillage and seeding of cancer cells into the peritoneal peritoneal cavity, thereby changing the stage and prognosis. Although definitive evidence supporting this notion is lacking, there have been many cases of aspirated malignant masses recurring along the needle tract through which the aspiration was done. Furthermore, there is strong evidence that spillage at the time of surgery decreases overall survival of stage I cancer patients compared with patients with tumors that were removed intact.
- An exception to avoiding aspiration of a mass exists for those patients who
  have clinical and radiographic evidence of advanced ovarian cancer and who
  are medically unfit to undergo surgery. In these women, malignant cytology
  confirmed in this fashion will establish a cancer diagnosis, thereby permitting
  initiation of neoadjuvant chemotherapy.

# **Laparoscopic Surgery**

In general, if a mass is suspicious for cancer based on transvaginal ultrasound findings, CA 125 levels, and clinical assessment, laparoscopic surgery usually is considered contraindicated, although laparoscopic staging and management of ovarian cancer have been reported.

# **QUALIFYING STATEMENTS**

#### **QUALIFYING STATEMENTS**

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

#### **IMPLEMENTATION OF THE GUIDELINE**

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

#### **IMPLEMENTATION TOOLS**

Audit Criteria/Indicators Foreign Language Translations Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

Getting Better Living with Illness

#### **IOM DOMAIN**

Effectiveness Patient-centeredness

#### **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

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#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

# **DATE RELEASED**

2007 Jul

# **GUIDELINE DEVELOPER(S)**

American College of Obstetricians and Gynecologists - Medical Specialty Society

# **SOURCE(S) OF FUNDING**

American College of Obstetricians and Gynecologists (ACOG)

#### **GUIDELINE COMMITTEE**

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins - Gynecology

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: <a href="mailto:sales@acog.org">sales@acog.org</a>. The ACOG Bookstore is available online at the <a href="mailto:ACOG Web site">ACOG Web site</a>.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

Proposed performance measures are included in the original guideline document.

# **PATIENT RESOURCES**

The following is available:

• Cancer of the ovary. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2007.

Electronic copies: Available from the <u>American College of Obstetricians and Gynecologists (ACOG) Web site</u>. Copies are also available in Spanish.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: <a href="mailto:sales@acog.org">sales@acog.org</a>. The ACOG Bookstore is available online at the ACOG Web site.

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#### NGC STATUS

This NGC summary was completed by ECRI Institute on July 30, 2008. The information was verified by the guideline developer on August 20, 2008.

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